

REMARKS

Claims 14-43 were previously pending in this application. Claims 14-15 have been canceled and amend pending claims 16, 18-26 and 35-36 have been amended. As a result claims 16-43 are pending for examination with claims 16, 18, 19, 20, 26, and 36 being independent claims. Claims 16 and 18-20 were amended to incorporate the language of former independent claim 14 and are now independent claims. Claims 21-25 were amended to correct the dependency discrepancy created with the cancellation of claim 14. Claims 26 and 35-36 were amended as discussed in the interview with the examiner, as described below. No new matter has been added.

Interview with Examiner Siew

Applicant thanks Examiner Siew for the courtesy of conducting a telephone interview with Applicant's representative, Helen Lockhart on March 19, 2004. The rejections under 102 and 112 were discussed in the interview. Briefly, the basis for the rejection was discussed and based on the conclusions of that discussion the amendments of claims 26 and 35-36 were proposed. The proposed amendments appeared to satisfy the outstanding rejections. Applicant, however, is aware of the Examiner's need to independently review the amendments prior to making any final decisions. The amendments to claims 16 and 18-25 were not discussed during the interview. Applicant is presenting these amendments to the Examiner for the first time in this document.

Rejection Under 35 U.S.C. §102

Claims 14-43 have been rejected under 35 U.S.C. 102(a) as being anticipated by Masoud et al. (J. Bacteriol., 1995, 6718-6726). The Examiner states that Masoud et al. teach the isolation of lipopolysaccharide core of *P. aeruginosa* and that the core contains an alanine. Based on the discussions during the telephone interview the Examiner indicated that the rejection was based on the teachings found on page 6718, column 2 relating to a commercially available prior art vaccine including LPS.

Applicants have amended claims 26 and 36 to clarify that the polysaccharide core is conjugated to a non toxic lipid or a bioactive agent that is not Lipid A, the lipid ordinarily found in LPS. Functional language was also included in claim 26 to clarify the purpose of the lipid conjugated to the polysaccharide core. Support for this language is found in the specification on pages 11-14 which describe the non-toxic lipid and the bioactive agent. Support in particular for the indication that Lipid A is excluded is found on page 13 lines 7-10. Support for the function of the lipid in the conjugate is found on page 11 lines 13-15 and page 12 line 23 – page 13 line 6. The claim amendments are sufficient to overcome the rejection based on a vaccine including an LPS molecule having Lipid A, because the conjugates include a core polysaccharide conjugated to a non-Lipid A material.

Applicant has canceled claims 14 – 15 and amended claims 16 and 18-20 to include all of the limitations of claim 14 as well as the limitation that the material is free of lipid A. Amended independent claims 16 and 18-20 are not anticipated by the polysaccharide core structure described in Masoud et al. For instance, the core structures shown in Figure 8 and 9 are linked to Lipid A or KDO. Additionally, the polysaccharide core structure of Masoud, as shown in Figures 8 and 9 is different than the polysaccharide core structures of claims 16 and 18-20. The linkage between X and Glc, is listed in amended claim 16 as a $1\rightarrow 6\beta$ linkage. This is distinct from the core structures shown in Figure 8 and 9 that have the other components of claim 16. The o3 core structure of Figure 9 has a $\beta\ 1-6$ linkage but lacks the second Hep. Support for these amendments is found in the original claims as filed. Support in particular for the indication that Lipid A is excluded is found on page 13 lines 7-10. Thus, Masoud et al. does not anticipate all the elements of the amended claims 16-25.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection under 112

Claims 35-43 have been rejected under 35 USC 112 because of the amendment introduced in the response to the last office action (received by the USPTO on October 3, 2003). Applicant has now removed the same limitations that were added. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Gerald B. Pier, Applicant

By: 

Helen C. Lockhart, Reg. No.39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

Docket No. B0801.70155US00
Date: April 29, 2004
x04/29/04x